



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

AUG 31 2004

Ryan Baidya, Ph.D., MBA
President and CEO
BioZak, Inc.
50 E. St. John Street, #203
San Jose, California 95112

Dear Dr. Baidya:

This is in response to your letter dated August 3, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that BioZak, Inc. intends to make claims about the effects of several products on breathing and lung/respiratory function. The products bear the following names, among others:

Allergy-Naso, Aller-zak, Aller-zoco, Allerzy-CLR, Allergenex, Allergyme-Naso, Allergenix, Aller-Ease, Hay-Go-Away, Allergen, and Ease the Sneeze.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these product, namely the names of the products that use the disease name allergy in the product name or which incorporate clearly recognizable transformations of the term "allergen" or symptoms of allergies in the product names suggest that they are intended to treat, prevent, or mitigate a disease, namely allergies. The claims you are making for these products do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

975-0163

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Please contact us if we may be of further assistance.

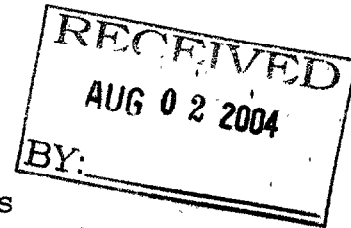
Sincerely yours,

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, San Francisco District Office, Office of Compliance, HFR-PA140

July 22, 2004

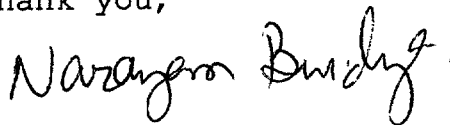


The Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling and Dietary
Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration,
5100 Paint Branch Parkway,
College Park, MD 20740-3835

Dear Sir/Madam,

Enclosed herewith please find a Notice of Statements
pursuant to 21 U.S.C. 403(r)(6).

Thank you,



Ryan Baidya, PhD, MBA
President & CEO

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**SECRETARY OF HEALTH AND HUMAN SERVICES
UNITED STATES OF AMERICA**

NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r)(6)

To: The Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration,
5100 Paint Branch Parkway, College Park, MD 20740-3835 USA

Date: July 22, 2004.

Re: This Notice covers the following Brand(s):

Allergy-Naso, Aller-zak, Aller-zoco, Allerzy-CLR, Allergenex, Allergyme-Naso, Allergenix, Aller-Ease, Hay-Go-Away, Ease, Allergen, Ease the Sneeze.

PLEASE TAKE NOTICE under 21 U.S.C. 403(r) (6):

(i) The name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement(s): **BioZak, Inc.**

50 E. St. John St., #203, San Jose, CA 95112

(ii) The text of the statement that is being made: see attached Exhibit A.

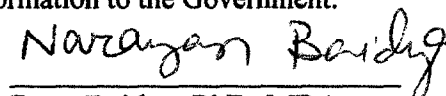
(iii) The name of the dietary ingredient or supplement that is the subject of the statement: see attached Exhibit A.

(iv) The name of the dietary supplement (including brand name), if not provided in response to paragraph (a)(2)(iii) on whose label, or in whose labeling, the statement appears: see attached Exhibit A.

CERTIFICATION

The undersigned, being duly authorized by the firm submitting the above Notice of Statements under 21 U.S.C. 403 (r) (6) certifies, as of the date first written above: (a) that the information contained in the Notice is complete and accurate, and (b) that the notifying firm has substantiation that the Statement(s) to which this Notice applies is truthful and not misleading.

The undersigned certifies that the above Certification is true and is aware that the undersigned is subject to punishment as for perjury if the Certification is willfully false. This Certification is made under 18 USC 1001 which makes it a crime to submit false information to the Government.


Ryan Baidya, PhD, MBA
President & CEO

NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r)(6)
Exhibit A

1. Brand Name(s) Included herein:

Allergy-Naso, Aller-zak, Aller-zoco, Allerzy-CLR, Allergenex, Allergyme-Naso, Allergenix, Aller-Ease, Hay-Go-Away, Ease, Allergen, Ease the Sneeze.

2. Dietary Ingredients or Supplements Included herein:

Vitamin C 60 mg
Vitamin B12 50 mcg

Proprietary herb blend. 565 mg
Ganoderma Lucidium
Cordyceps Sinensis
Cryptoporus Volvatus
Agaricus Blazei Murill
Xylaria Nigripes
Ginkgo Biloba
Ginseng

3. Statements made with regard to the Ingredients:

Balances the immune system that helps one to enjoy good health, a clear day & pleasant breathing.

Vitamins and herbs work together to promote a relaxed feeling; and gently soothe away tension and that irritability that ruins a day

Herbal-blend and vitamin C support the immune system for harmonized-response

Maintains healthy lung/respiratory function to enjoy pleasant breathing

Herbs mix provides stamina and vitality

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